ORIGINAL

DOCKET FILE COPY ORIGINAL

Before the

FEDERAL COMMUNICATIONS COMMISSION

Washington, D.C. 20554

In the Matter of	)	
	)	
Amendment of Parts 2 and	)	
95 of the Commission's Rules	)	
To Establish the Medical Implant	)	RM No. 9157
Communications Service in the	)	
402 - 405 MHz Band	)	

To: The Commission

REPLY COMMENTS OF MEDTRONIC, INC.

Medtronic, Inc., by its attorneys and pursuant to Section 1.405 of the Commission's Rules, hereby submits these comments in reply to the comments filed in response to Medtronic's Petition for Rule Making, which urged the Commission to propose regulations that would establish the Medical Implant Communications Service ("MICS") in the 402 - 425 MHz band. For the reasons set forth in the comments and the petition, Medtronic urges the Commission to issue promptly a notice of proposed rule making calling for the creation of the requested radio service.

All of the comments filed in response to the petition were positive. The commenters urged the Commission to move forward with the proposal. Each of the commenters noted ways in which Medtronic's proposal could serve the public interest. Various of the comments discuss the need for improvements in the way data are transferred to and from implanted medical devices.

Dr. George Klein of the The University of Western Ontario Department of Medicine noted that "[t]he ability to interrogate and program these devices to function optimally is critical to their intelligent usage. Current inductive systems require an intimate contact between the programming head and the implant site and are becoming increasingly inadequate for current usage. The proposed petition would allow for the development of a system that enables device manipulation from a distance which could result in a considerable ease in the burden that these patients face for device follow-up and optimal usage. This system would represent a great stride forward in the provision of the best technology available to our patients."[1]

Dr. Ben Johnson, Director of Electrophysiology Services of the Iowa Heart Center, noted that improvements in data collection and storage have led to the need for the sorts of communications systems that MICS will support. According to Dr. Johnson,"[a]dvances will be in additional information storage (almost incomprehensible increases) by the implanted device, multiple-sensor integration into the functionality and capabilities of these devices and increased capability for remote (off-site) data retrieval and even potential device programming. Such advances will require rapid information transfer to and from the patient and healthcare professional-operated device programmers."[2]

Dr. David Steinhaus explained that the capabilities that better wireless links would bring to medical implants would translate into improvements in the cost effectiveness of treatment. He went on to highlight the patient benefits in terms of decreased intrusiveness and greater ability to maintain the sterile field at the time of implantation.[3]

---

[1] Comments of George J. Klein, M.D.
[2] Comments of W. Ben Johnson, M.D.
[3] Comments of David M. Steinhaus, M.D.

Dr. Edward Platia, Director of the Cardiac Arrhythmia Center, of the Washington Hospital Center explained in his comments that a system providing for a two meter range would allow for a "significant advance in communication with implanted medical devices in a manner that is significantly more efficient than current systems."[4] Dr. Platia went on to characterize the current telemetry systems in implanted devices as "somewhat of a weak link in recent times, as electronic advances have permitted rapidly increasing patient data that the devices collect."[5]

Dr. Douglas Zipes of the Indiana University School of Medicine urged the Commission to go forward with the Medtronic proposal as being in the public interest because MICS would support systems that "would enhance patient care and improve treatment options by affording communication with implantable medical services in a manner that is significantly more efficient than current systems."[6]

Finally, Dr. Marshall Stanton of the Mayo Clinic, writing as "a cardiologist who cares for a large number of patients with medical problems that would be affected by this rule" expressed the view "that creation of the MICS is vitally in the public interest as it will: 1) allow advanced diagnostic and treatment options that are not currently available in medical devices, 2) decrease the time that patients need to spend in physician's offices, [and] 3) reduce the cost of providing medical care."[7] Dr. Stanton concluded by urging the Commission to move forward to enact rules to create MICS. According to Dr. Stanton, "Failure to do so will greatly limit major advances in the care of patients with serious heart disease."[8]

---

[4] Comments of Edward V. Platia, M.D.
[5] *Id.*
[6] Comments of Douglas P. Zipes, M.D.
[7] Comments of Marshall S. Stanton, M.D.
[8] *Id.*

Every year, hundreds of thousands of Americans die from cardiovascular disease. The Medical Implant Communications Service will provide physicians with another valuable tool in fighting the tragedy that heart disease visits upon the American public. MICS will also support diagnosis and treatment options for a wide variety of other diseases and disabilities. Making spectrum available for MICS will fuel innovation from Medtronic and others as communications and information technologies are brought to bear in the alleviation of suffering in this country and around the world. For these reasons, Medtronic urges the Commission to move without delay to issue a notice of proposed rule making setting forth proposed regulations that, upon adoption in final form, will make the Medical Implant Communications Service a reality. This use of spectrum would be in the highest tradition of using radio for the protection of life.

Respectfully submitted

MEDTRONIC, INC.

by David E. Hilliard

David E. Hilliard

of

Wiley, Rein & Fielding
1776 K Street, N.W.
Washington, D.C. 20006
202-429-7058
202-429-7049 (fax)

October 14, 1997

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of October , 1997, I caused copies of the foregoing Reply Comments of Medtronic, Inc. to be mailed via first-class postage prepaid mail to the following:

W. Ben Johnson, M.D.
Director of Electrophysiology Services
Iowa Heart Center
411 Laurel, Suite #1250
Des Moines, Iowa 50314

George J. Klein, M.D.
Chair, Division of Cardiology
The University of Western Ontario
Room 2C19
339 Windermere Road
London, Ontario
Canada N6A 5A5

Edward V. Platia, M.D.
Director, Cardiac Arrhythmia Center
Washington Hospital Center
110 Irving Street, N.W.
Washington, D.C. 20010

Marshall S. Stanton, M.D
Mayo Clinic
200 First Street SW
Rochester, Minnesota 55905

David M. Steinhaus, M.D.
Cardiovascular Consultants, P.C.
4330 Wornall Road, Suite 2000
Kansas City, MO 64111

Douglas P. Zipes, M.D.
Distinguished Professor of Medicine
Pharmacology and Toxicology
Iowa Heart Center
411 Laurel Street, Suite #1250
Des Moines, Iowa 50314-3046

Bridgette T. Graves